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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/018,128	03/11/2002	Dennis M. Martin	550.0122USQ1	1510

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EXAMINER

DI NOLA BARON, LILIANA

ART UNIT	PAPER NUMBER
1615	

DATE MAILED: 05/04/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>
	10/018,128	MARTIN ET AL.
	<b>Examiner</b>	<b>Art Unit</b>
	Liliana Di Nola-Baron	1615

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1) Responsive to communication(s) filed on 18 February 2004.  
 2a) This action is **FINAL**.                    2b) This action is non-final.  
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4) Claim(s) 1 and 7-19 is/are pending in the application.  
 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.  
 5) Claim(s) \_\_\_\_\_ is/are allowed.  
 6) Claim(s) 1 and 7-19 is/are rejected.  
 7) Claim(s) \_\_\_\_\_ is/are objected to.  
 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

9) The specification is objected to by the Examiner.  
 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
 a) All    b) Some \* c) None of:  
     1. Certified copies of the priority documents have been received.  
     2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
     3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) <input type="checkbox"/> Notice of References Cited (PTO-892)	4) <input type="checkbox"/> Interview Summary (PTO-413)
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	Paper No(s)/Mail Date. _____ .
3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____ .	5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)
	6) <input type="checkbox"/> Other: _____ .

## **DETAILED ACTION**

Receipt of Applicant's amendment, filed on February 18, 2004, is acknowledged.

### ***Claim Rejections - 35 USC § 102***

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1 and 7-19 are rejected under 35 U.S.C. 102(b) as being anticipated by Bush et al. (U.S. Patent 5,364,617).

Bush et al. provides compositions and method for protecting the skin from the harmful effects of ultraviolet radiation, said effects comprising the premature aging of the skin, characterized, among others, by wrinkling and yellowing of the skin, cracking and loss of elasticity (See col. 1, lines 10-43).

With respect to the limitations of claim 1, that the claimed method of the invention is directed to the epithelia, and specifically to the lips, and the composition is applied to the epithelia for an effective period of time, the patent teaches that the topical compositions of the invention may be formulated in the form of lipsticks (See col. 18, lines 27-29) and provides a method comprising topical application of a stick to the lips to inhibit damage caused by acute or chronic UV exposure (See Example IV). Furthermore, the patent discloses a method and compositions for

preventing the deleterious effects caused by UV exposure comprising applying to the skin compositions comprising a retinoid prior to, during or after UV exposure (See col. 25, lines 11-18 and col. 26, lines 5-21) Thus, the patent discloses a method comprising application of the topical composition of the invention to the epithelia, i.e. the lips, for an effective period of time, as claimed by Applicant.

With respect to the method of improving the aesthetic appearance of epithelia claimed in claim 1, Bush et al. teaches that ultraviolet radiation causes premature aging of the skin (See col. 1, lines 36-38), discloses the use of a topical composition to prevent photoaging effects of exposure to the sun (See col. 4, lines 22-25) and provides a method comprising topical application of a stick to the lips to inhibit damage caused by acute or chronic UV exposure (See Example IV). Thus, the patent contemplates a method of improving the aesthetic appearance of epithelia, as claimed in claim 1 of the instant application.

With regard to the improvement results claimed in claim 1 of the instant application, Bush et al. teaches that the premature aging caused by ultraviolet radiation is characterized, among others, by wrinkling and yellowing of the skin, cracking and loss of elasticity (See col. 1, lines 37-43). The patent discloses a method and compositions for preventing the deleterious effects caused by UV exposure comprising applying to the skin compositions comprising a retinoid prior to, during or after UV exposure (See col. 25, lines 11-18 and col. 26, lines 5-21) and provides a method comprising topical application of a stick to the lips to inhibit damage caused by acute or chronic UV exposure (See Example IV). Since the method disclosed in the patent prevents premature

photoaging, including wrinkling and yellowing of the skin, cracking and loss of elasticity, and is effective on lips, it inherently improves lip color and clarity by inhibiting yellowing, decreases lip dryness by preventing loss of elasticity and reduces vertical lip lines by decreasing wrinkling and cracking, as claimed by Applicant in claim 6.

Regarding the retinoid claimed in the method of claim 1 and the composition of claim 18, Bush et al. teaches that the photoprotection compositions of the invention preferably include a retinoid, which increases the wrinkle regulating benefits of the compositions (See col. 24, lines 63-68).

With respect to the penetration enhancing agent claimed in the method of claim 1 and the composition of claim 18, Bush et al. teaches that the topical compositions of the invention comprise an effective amount of 1-5% of the composition of a penetration enhancing agent (See col. 18, lines 43-55).

With regard to the amount of retinoid claimed in claim 7 of the instant application, Bush et al. teaches that a safe and effective amount of a retinoid in the compositions of the invention is 0.001-2% of the composition (See col. 24, line 68 to col. 25, line 4). Thus, the patent discloses an amount range of retinoid as claimed by Applicant.

With respect to the limitation of claim 8, that the retinoid is retinol, Bush et al. includes Vitamin A among the retinoids used in the invention (See col. 25, lines 4-10). Retinol and Vitamin A are synonymous.

Regarding the penetration enhancing agents claimed in claims 9 and 10 of the instant application, Bush et al. includes organic solvents, and specifically propylene glycol and ethanol in the compositions of the invention (See col. 16, lines 23-45).

With respect to the cosmetically acceptable vehicle claimed in claims 11 and 12 of the instant application, Bush et al. teaches that the compositions of the invention may be made into a variety of products, including gels, sticks, sprays, pastes and cosmetics, which comprise solutions or emulsions (See col. 16, lines 15-22 and lines 46-63, and col. 17, line 2 to col. 18, line 29).

With regard to the limitation of claim 13, that the composition has a pH less than about 7.5, Bush et al. provides a method for the preparation of an emulsion useful for topical application to inhibit damage caused by acute or chronic UV exposure, and teaches that the pH of the emulsion is brought to 6.5 (See Example IX, col. 32, lines 7-20). Thus, the patent provides compositions having a pH less than 7.5, as claimed by Applicant.

Regarding the anhydrous vehicle claimed in claim 14 of the instant application, Bush et al. provides solutions comprising organic solvents (See col. 16, lines 23-40) and discloses an ointment as carrier system, comprising animal or vegetable oils or oleaginous hydrocarbons (See col. 17, lines 18-21). The ointments comprising oils and the solutions containing organic solvents disclosed by the prior art are anhydrous vehicles, as claimed by Applicant in claim 14 of the application.

With respect to the secondary component claimed in claim 15, and specifically the sunscreen agents claimed in claims 16, 17 and 19 of the present application, Bush et al. teaches that preferred photoprotection compositions comprise a sunscreen agent and a retinoid (See col. 25, lines 11-18) and includes titanium dioxide among the sunblocks used in the invention and 2-ethylhexyl p-methoxycinnamate and butylmethoxydibenzoylmethane among the preferred sunscreens used in the compositions and method of the invention (See col. 20, line 35 to col. 21, line 38). The 2-ethylhexyl p-methoxycinnamate disclosed by the prior art corresponds to the octylmethoxycinnamate claimed by Applicant (the two terms are synonymous), and the butylmethoxydibenzoylmethane disclosed by the prior art is the chemical term for the compound avobenzone claimed by Applicant. Thus the patent provides the use of secondary components, and specifically sunscreens, as claimed by Applicant in claims 15-17 and 19 of the instant application.

The method and compositions disclosed by Bush et al. meet the limitations of claims 1 and 7-19 of the instant application, as the patent contemplates compositions comprising a retinoid and a penetration agent, and further comprising a sunscreen agent., and a method comprising applying said compositions to the lips. Thus, the patent anticipates the claimed invention.

***Response to Arguments***

3. Applicant's arguments filed on February 18, 2004 have been fully considered but they are not persuasive.

4. Applicant argues that the lipstick disclosed in Example IV of Bush et al. does not include a retinoid and/or penetration enhancing agent, and the retinoids in Bush et al. are disclosed as optional ingredients. In response to said argument, it is noted that Bush et al. teaches that the photoprotection compositions of the invention preferably include a retinoid, which increases the wrinkle regulating benefits of the compositions (See col. 24, lines 63-68), and comprise an effective amount of 1-5% of the composition of a penetration enhancing agent (See col. 18, lines 43-55). Thus the prior art specifically teaches that the compositions of the invention preferably comprise retinoids and penetration enhancing agents. The examples in the prior art are the inventor's best mode. It is not necessary for the prior art to disclose each and every component claimed by Applicant in the examples, as long as the prior art provides the teachings that the compositions of the invention comprise retinoids and penetration enhancing agents.

5. In response to Applicant's argument, that Bush et al. does not attribute any improvement in lip epithelia esthetics to the presence of retinoids, it is noted that Bush et al. teaches that the photoprotection compositions of the invention preferably include a retinoid, which increases the wrinkle regulating benefits of the compositions (See col. 24, lines 63-68). The effects claimed by Applicant are inherent to the presence of retinoids in the compositions disclosed by the prior art.

***Conclusion***

6. Claims 1 and 7-19 stand rejected.
7. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Liliana Di Nola-Baron whose telephone number is 571-272-0592. The examiner can normally be reached on Monday through Thursday, 8:30AM-7:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K Page can be reached on 571-272-0602. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

*SN83*

April 22, 2004

*[Signature]*  
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